

K130215

510(k) Premarket Notification  
GORE® ACUSEAL Vascular Graft  
510(k) Summary of Substantial Equivalence

APR 09 2013

# 510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name: GORE® ACUSEAL Vascular Graft

Common Name: Vascular Graft

Classification Name: Prosthesis, Vascular Graft, 6 mm and greater diameter  
Prosthesis, Vascular Graft, of less than 6 mm in diameter  
(per 21 CFR 870.3450)

Device Classification: Class II

Product Classification and Code: DSY

Classification Panel: Cardiovascular Devices

Establishment Registration Number: 2017233

Contact Person: Michael Ivey  
Regulatory Affairs  
Medical Products Division  
W.L. Gore and Associates  
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Flagstaff, AZ 86001  
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## Performance Standards

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There are no applicable standards with recognized performance criteria that currently exist for these devices. None are established under Section 514.

## Device Description

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The GORE® ACUSEAL Vascular Graft is a multilayer graft design comprised of expanded polytetrafluoroethylene (ePTFE) separated by an elastomeric layer and may be available both with and without covalently bound bioactive heparin on the luminal surface of the

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device (commonly known as the Carmeda® BioActive Surface, or CBAS® heparin). The GORE® ACUSEAL Vascular Graft is intended for use as a vascular prosthesis in patients requiring vascular access.

## Indications for Use

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The GORE® ACUSEAL Vascular Graft is intended for use as a vascular prosthesis in patients requiring vascular access.

## Substantially Equivalent Devices

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The following devices as substantially equivalent predicate devices listed below:

- GORE® PROPATEN® Vascular Graft (K062161)
- GORE-TEX® Stretch Vascular Graft (K903931)
- Vascutek® Ltd SEALPTFE™ ePTFE Vascular Prosthesis (K030999)

## Brief Comparison Summary

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To demonstrate substantial equivalence of the applicant GORE® ACUSEAL Vascular Graft to the predicate devices, technological characteristics and performance criterion were evaluated using *in vitro* and *in vivo* testing as indicated below:

### *In Vitro* Testing

Using FDA guidance documents on non-clinical testing of medical devices the following *in vitro* tests were performed:

- Wall Thickness
- Internal Diameter
- Suture Retention (transverse and longitudinal)
- Kink Radius (Pressurized and Non-Pressurized)
- Punctured Burst
- Punctured Leak
- Burst Testing
- Fibril Length
- Water Entry Pressure (WEP)
- Tensile Strength Fibril Length
- Pressurized Internal Diameter

The *in-vitro* test results of GORE® ACUSEAL Vascular Graft and the other predicate devices demonstrate that the technological characteristics and performance criteria of the devices are comparable and equivalent and that GORE® ACUSEAL Vascular Graft can perform in a manner equivalent to devices currently available on the market.

### ***In Vivo* Animal Testing**

To further assess the performance of the GORE® ACUSEAL Vascular Graft, as well as evaluate the biocompatibility of the graft in a vascular application, an *in vivo* study was conducted in a canine model to evaluate 4 device attributes:

- **Intra-Operative Suture Line Bleeding:** The implanted device demonstrates equivalent intra-operative suture line bleeding compared to currently marketed devices
- **Post-Cannulation Time-to-Hemostasis:** the device achieves hemostasis successfully post cannulation and allows for closure of the incision site by the surgeon.
- **Device Patency:** The implanted device remains patent and in position throughout the in-life period in the canine model.
- **Histological Response:** device demonstrates tissue response similar to currently marketed grafts.

*In vivo* animal results demonstrate that the GORE® ACUSEAL Vascular Graft had no intra-operative suture line bleeding during implant. Devices achieved hemostasis successfully post cannulation in that the test devices had a time-to-hemostasis comparable to or significantly lower than that of the predicate devices. Angiographic imaging demonstrated that the devices remained widely patent throughout the in-life period in the canine model. CT scans showed no evidence of device kinking during the in-life period. The histological profile of the GORE® ACUSEAL Vascular Graft was comparable to predicate vascular grafts.

### ***In Vivo* Clinical Data**

A 138-subject, multi-centered, prospective, single arm clinical trial was conducted to compare the GORE® ACUSEAL Vascular Graft to historical controls in patients requiring arteriovenous access grafts for hemodialysis.

The primary efficacy endpoint was cumulative patency at 6 months, determined by hemodynamic evidence of blood flow. The primary safety endpoint was freedom from bleeding at 6 months defined as percent of subjects free from major or minor bleeding including hematoma, incision site bleeding, gastrointestinal bleeding, rectal bleeding, and hemoptysis. The study also documented the time to first hemodialysis access and first three consecutive hemodialysis sessions.

At the end of the 6-month follow-up, the primary endpoint of cumulative patency for the GORE® ACUSEAL Vascular Graft was 84% compared to the historical control of 75%. The secondary endpoint of primary unassisted patency for the GORE® Vascular Graft was 46% compared to the historical control of 42%. In addition, freedom from bleeding (defined as any occurrence of reported bleeding from any source including but not limited to gastrointestinal bleeds, hemoptysis, extravasations, incision site bleeds, etc) was 88% in the GORE® ACUSEAL Vascular Graft group

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compared to 78% in the historical control group. There were no device related adverse events or device related deaths reported in the study.

As part of a secondary endpoint of the GORE® ACUSEAL Vascular Graft clinical study, the time from initial graft implantation of the graft to the time of first cannulation was collected and analyzed. This data is summarized below:

**Table 1: Time to First Cannulation post Graft Implantation**

<b>Time till Graft Cannulation</b>	<b>Number of ACUSEAL Grafts Cannulated</b>
24 Hours	N=30/135 (22.2%)
48 Hours	N=48/135 (35.6%)
72 Hours	N=54/135 (40.0%)
7 Days	N=70/135 (51.9%)

The median days to first cannulation through the study graft was 5 days with a range of 0-116 days. For patients cannulated within the first 24 hours, the median time to first cannulation of the study graft was 21 hours with a range of 2 hours to 24 hours.

An additional secondary endpoint of the GORE® ACUSEAL Vascular Graft clinical study, for the subjects presenting with a central venous catheter (CVC), the time from initial graft implantation to the third consecutive use of the graft for hemodialysis was collected and analyzed. Within 28 days of graft implantation 75.6% of the implanted GORE® ACUSEAL Vascular Grafts had been successfully cannulated 3 consecutive times and allowing for the potential for the CVC catheter to be removed.

The clinical data demonstrate that the GORE® ACUSEAL Vascular Graft has comparable clinical performance to that of the predicate grafts.

## **Conclusion (Statement of Equivalence)**

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W. L. Gore and Associates believes that the data presented in this application, including *in vitro* testing, *in vivo* data, along with numerous device similarities support a determination of substantial equivalence, and therefore market clearance of the GORE® ACUSEAL Vascular Graft through this 510(k) Premarket Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 9, 2013

W. L. Gore & Associates, Inc.  
Attn: Mr. Michael Ivey  
Regulatory Affairs  
Medical Products Division  
3250 W. Kiltie Lane  
Flagstaff, AZ 86001

Re: K130215  
Trade/Device Name: GORE® ACUSEAL Vascular Graft  
Regulation Number: 21 CFR 870.3450  
Regulation Name: Vascular Graft Prosthesis  
Regulatory Class: Class II  
Product Code: DSY  
Dated: January 28, 2013  
Received: January 29, 2013

Dear Mr. Ivey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew brenner

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

# INDICATION FOR USE

**510(k) Number (if  
known):**

**K130215**

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**Device Name:**

GORE® ACUSEAL Vascular Graft

**Intended Use / Indication  
For Use:**

The GORE® ACUSEAL Vascular Graft is intended for use as a vascular prosthesis in patients requiring vascular access.

**X**

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Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER  
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Matthew G. Hillebrenner**